Alternative Standards
(11/1/99)

1. Conducting the daily processor QC tests when the sensitometer is not available

This alternative standard was approved on October 18, 1999 and was made retroactive to April 28, 1999. The alternative to sensitometric-densitometric testing of processor performance can be used for a period of up to two weeks when the facility's sensitometer is unavailable. This alternative is based on evaluating a phantom image through measurements described in 21 CFR 900.12(e)(1) and (2).

The final regulation and its alternative standard are stated below:

21 CFR 900.12(e)(1) and (2) states that:

(1) Daily quality control tests. Film processors used to develop mammograms shall be adjusted and maintained to meet the technical development specifications for the mammography film in use. A processor performance test shall be performed on each day that clinical films are processed before any clinical films are processed that day. The test shall include an assessment of base plus fog density, mid-density, and density difference, using the mammography film used clinically at the facility.

(i) The base plus fog density shall be within + 0.03 of the established operating level.

(ii) The mid-density shall be within +/- 0.15 of the established operating level.

(iii) The density difference shall be within +/- 0.15 of the established operating level.

(2) Weekly quality control tests. Facilities with screen-film systems shall perform an image quality evaluation test, using an FDA-approved phantom, at least weekly.

(i) The optical density of the film at the center of an image of a standard FDA-accepted phantom shall be at least 1.20 when exposed under a typical clinical condition.

(ii) The optical density of the film at the center of the phantom image shall not change by more than +/- 0.20 from the established operating level.

(iii) The phantom image shall achieve at least the minimum score established by the accreditation body and accepted by FDA in accordance with Sec. 900.3(d) or Sec. 900.4(a)(8).

(iv) The density difference between the background of the phantom and an added test object, used to assess image contrast, shall be measured and shall not vary by more than +/- 0.05 from the established operating level.

When using the alternative test, processor performance is considered satisfactory if:

1. The optical density of the film at the center of an image of a standard FDA-accepted phantom is at least 1.20 when exposed under typical clinical conditions.
2. The optical density of the film at the center of the phantom image changes no more than +/- 0.20 from the established operating level.

3. The density difference between the background of the phantom and an added test object, used to assess image contrast, is measured and does not vary by more than +/-0.05 from the established operating level.

In addition:

4. To evaluate base + fog, an additional measurement of density must be made either of a shielded portion of the phantom image film or of an unexposed film. In accordance with 21 CFR 900.12(e)(1)(i), the base plus fog density must be within + 0.03 of the established operating level.

This alternative test must be conducted "each day clinical films are processed, but before processing of clinical films." All results must be recorded and charted. If processor performance fails to meet any part of the alternative test, the problem must be corrected before processing is resumed.

2. Continuous display of the override status for machines with decompression devices

This alternative standard was approved on June 22, 1999 and was made retroactive to April 28, 1999. It has no time limit.

The final regulation and its alternative standard are stated below:

21 CFR 900.12(e)(5)(xi) states that:

(xi) Decompression. If the system is equipped with a provision for automatic decompression after completion of an exposure or interruption of power to the system, the system shall be tested to confirm that it provides:

(A) An override capability to allow maintenance of compression;

(B) A continuous display of the override status; and

(C) A manual emergency compression release that can be activated in the event of power or automatic release failure.

The approved alternative standard to 21 CFR 900.12(e)(5)(xi)(B) allows facilities having machines equipped with automatic decompression devices that are never disabled to permanently place a label on the panel indicating that the unit must always be operated in the automatic decompression mode, in lieu of a continuous display of the automatic decompression override status required in 21 CFR 900.12(e)(5)(xi)(B). The wording of this label must be:

Unit always to be used in auto release mode. If auto release is overridden this status will not be displayed.

3. Conducting the weekly phantom image test at facilities with intermittent mammography operation

This alternative standard was approved on May 24, 1999 and was made retroactive to April 28, 1999. It applies to facilities that do not conduct mammography every week. Rather, they may conduct mammography during some, but not all, weeks in a given month.

The final regulation and its alternative standard are stated below:

21 CFR 900.12(e)(2) states that:

> *(2) Weekly Quality Control Tests. Facilities with screen-film systems shall perform an image quality evaluation test, using a FDA-approved phantom, at least weekly.*

The approved alternative standard is:

(2) Weekly Quality Control Tests. Facilities with screen-film systems shall perform an image quality evaluation test, using an FDA-approved phantom, in each week that clinical mammography examinations are performed, prior to the performance of such examinations.

The alternative standard requires that if the number of weeks per month in which clinical mammography is performed increases or decreases, the frequency of the performance of the phantom image quality test must automatically undergo a corresponding increase or decrease. Because of this automatic adjustment to changing facility conditions, no time limit has been placed upon the period of approval.

4. Post exposure indication of the machine pre-selected focal spot and or target material

This alternative standard was approved on April 19, 1999 and became effective on April 28, 1999 for Senographe^{TM} DMR GE machines.

The final regulation and its alternative standard are stated below:

21 CFR 900.12(b)(7) states that:

> *(7) Focal spot selection.*
> *(i) When more than one focal spot is provided, the system shall indicate, prior to exposure, which focal spot is selected.*
> *(ii) When more than one target material is provided, the system shall indicate, prior to exposure, the preselected target material.*
> *(iii) When the target material and/or focal spot is selected by a system algorithm that is based on the exposure or on a test exposure, the system shall*

display, after the exposure, the target material and/or focal spot actually used during the exposure.

The approved alternative is:

(7) Focal spot selection.

(i) When more than one focal spot and/or more than one target material is provided, the system shall indicate, prior to exposure, the pre-selected focal spot and target material, and shall indicate, after the exposure, the focal spot and test material actually used during the exposure; or

(ii) When the target material and/or focal spot is selected by a system algorithm that is based on the exposure or on a test exposure, the system shall indicate, after the exposure, the target material and/or focal spot actually used during the exposure."

Under the approved alternative, an indication of the pre-exposure focal spot and target material would no longer be required when the pre-exposure target material and focal spot are set by a system algorithm based on exposure and the user has no control over that selection. In operating modes where the user has control of the pre-selected focal spot and/or target material, indication of the pre-selected values would still be required. In all cases, indication of the focal spot and/or target material actually used during the exposure would be required.